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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,320	03/28/2001	Henry E. Young	1304-1-019 CIP1	4118

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KLAUBER & JACKSON
411 Hackensack Avenue
Hackensack, NJ 07601

EXAMINER	
TON, THAIAN N	

ART UNIT	PAPER NUMBER
1632	7

DATE MAILED: 06/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/820,320	Applicant(s) YOUNG ET AL.	
	Examiner Thaian N. Ton	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If the period for reply specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is FINAL. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant is requested to review claim 32, as it appears to be improperly dependent.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17, drawn to pluripotent embryonic-like stem cells, cultures comprising the pluripotent embryonic-like stem cells, methods of isolating pluripotent embryonic-like stem cells and methods of producing a genetically engineered pluripotent embryonic-like stem cells, classified in class 800, subclasses 3, 8, 9, 11, 13, 18, class 424, subclass 93.21 and class 435, subclass 325, for example.

II. Claims 18-23, drawn to methods for detecting the presence or activity of an agent which is a lineage-commitment factor, method of testing the ability of an agent, compound, or factor to modulate the lineage-commitment of a lineage uncommitted cell, and an assay system for screening agents, compounds or factors for the ability to modulate lineage-commitment of a lineage uncommitted cell, wherein the lineage is determined by *mRNA expression*, classified in class 435, subclass 4.

III. Claims 18-23, drawn to methods for detecting the presence or activity of an agent which is a lineage-commitment factor, method of testing the ability of an agent, compound, or factor to modulate the lineage-commitment of a lineage uncommitted cell, and an assay system for screening agents, compounds or factors for the ability to modulate lineage-commitment of a lineage uncommitted cell, wherein the lineage is determined by *antigen expression*, classified in class 435, subclass 4.

IV. Claim 18-23, drawn to methods for detecting the presence or activity of an agent which is a lineage-commitment factor, method of testing the ability of an agent, compound, or factor to modulate the lineage-commitment of a lineage uncommitted cell, and an assay system for screening agents, compounds or factors for the ability to modulate lineage-commitment of a lineage uncommitted cell, wherein the lineage is determined by *other means*, unclassifiable.

V. Claim 24-28 and 31, drawn to methods of transplanting pluripotent embryonic-like stem cells into a host, and methods of prevent and/or treating cellular debilitations, derangements and/or dysfunctions and/or other disease states in mammals, classified in class 514, subclass 44.

VI. Claims 29-30 and 32, drawn to methods of preventing and/or treating cellular debilitations, derangements and/or dysfunctions and/or other disease states in mammals, comprising administering to a mammal a therapeutically effective amount of an endodermal, ectodermal or mesodermal lineage-committed cell derived from stem cells, classified in class 514, subclass 44.

Invention I and any of Inventions II-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the pluripotent embryonic-like stem cell can be used to produce transgenic animals.

Inventions II and any of Inventions III-VI are mutually exclusive and independent methods. The methods for detecting the presence or activity of an agent which is a lineage-commitment factor, method of testing the ability of an agent, compound, or factor to modulate the lineage-commitment of a lineage uncommitted cell, and an assay system for screening agents, compounds or factors for the ability to modulate lineage-commitment of a lineage uncommitted cell, wherein the lineage is determined by *mRNA expression* of Invention II is not

required for the methods for detecting the presence or activity of an agent which is a lineage-commitment factor, method of testing the ability of an agent, compound, or factor to modulate the lineage-commitment of a lineage uncommitted cell, and an assay system for screening agents, compounds or factors for the ability to modulate lineage-commitment of a lineage uncommitted cell, wherein the lineage is determined by *antigen expression* of Invention III, the methods for detecting the presence or activity of an agent which is a lineage-commitment factor, method of testing the ability of an agent, compound, or factor to modulate the lineage-commitment of a lineage uncommitted cell, and an assay system for screening agents, compounds or factors for the ability to modulate lineage-commitment of a lineage uncommitted cell, wherein the lineage is determined by *other means* of Invention IV, the methods of transplanting pluripotent embryonic-like stem cells into a host, and methods of prevent and/or treating cellular debilitations, derangements and/or dysfunctions and/or other disease states in mammals of Invention V, or the methods of preventing and/or treating cellular debilitations, derangements and/or dysfunctions and/or other disease states in mammals, comprising administering to a mammal a therapeutically effective amount of an endodermal, ectodermal or mesodermal lineage-committed cell derived from stem cells of Invention VI, and vice versa. Furthermore, each of the methods requires a materially different and separate protocol.

Invention III and any of Inventions IV-VI are mutually exclusive and independent methods. The methods for detecting the presence or activity of an agent which is a lineage-commitment factor, method of testing the ability of an agent, compound, or factor to modulate the lineage-commitment of a lineage uncommitted cell, and an assay system for screening agents, compounds or factors for the ability to modulate lineage-commitment of a lineage uncommitted cell, wherein the lineage is determined by *antigen expression* of Invention III are not required for the methods for detecting the presence or activity of an agent which is a lineage-commitment factor, method of testing the ability of an agent, compound, or factor to modulate the lineage-commitment of a lineage uncommitted cell, and an assay system for screening agents, compounds or factors for the ability to modulate lineage-commitment of a lineage uncommitted cell, wherein the lineage is determined by *other means* of Invention IV, the methods of transplanting pluripotent embryonic-like stem cells into a host, and methods of prevent and/or treating cellular debilitations, derangements and/or dysfunctions and/or other disease states in mammals of Invention V, the methods of preventing and/or treating cellular debilitations, derangements and/or dysfunctions and/or other disease states in mammals, comprising administering to a mammal a therapeutically effective amount of an endodermal, ectodermal or mesodermal lineage-committed cell derived from stem cells of Invention VI, and vice versa.

Furthermore, each of the methods requires a materially different and separate protocol.

Invention IV and any of Inventions V-VI are mutually exclusive and independent methods. The methods for detecting the presence or activity of an agent which is a lineage-commitment factor, method of testing the ability of an agent, compound, or factor to modulate the lineage-commitment of a lineage uncommitted cell, and an assay system for screening agents, compounds or factors for the ability to modulate lineage-commitment of a lineage uncommitted cell, wherein the lineage is determined by *other means* of Invention IV are not required for the implementation of the methods of transplanting pluripotent embryonic-like stem cells into a host, and methods of prevent and/or treating cellular debilitations, derangements and/or dysfunctions and/or other disease states in mammals of Invention V, or the methods of preventing and/or treating cellular debilitations, derangements and/or dysfunctions and/or other disease states in mammals, comprising administering to a mammal a therapeutically effective amount of an endodermal, ectodermal or mesodermal lineage-committed cell derived from stem cells of Invention VI, and vice versa. Furthermore, each of the methods requires a materially different and separate protocol.

Invention V and Invention VI are mutually exclusive and independent methods. The methods of transplanting pluripotent embryonic-like stem cells into a host, and methods of prevent and/or treating cellular debilitations, derangements

and/or dysfunctions and/or other disease states in mammals of Invention V are not required for the implementation of the methods of preventing and/or treating cellular debilitations, derangements and/or dysfunctions and/or other disease states in mammals, comprising administering to a mammal a therapeutically effective amount of an endodermal, ectodermal or mesodermal lineage-committed cell derived from stem cells of Invention VI, and vice versa. Furthermore, each of the methods requires a materially different and separate protocol.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thaian N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the

examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to Patsy Zimmerman, Patent Analyst, at (703) 305-2758. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-8724.

Deborah Crouch
DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800/1630

TNT

Thaian N. Ton
Patent Examiner
Group 1632